

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF CALIFORNIA

CITY AND COUNTY OF SAN  
FRANCISCO, et al.,

Plaintiffs,

v.

PURDUE PHARMA L.P., et al.,  
Defendants.

Case No. 18-cv-07591-CRB

**ORDER TO SHOW CAUSE**

On August 10, 2022, the Court issued its Findings of Fact and Conclusions of Law (FOFCOL), holding that Walgreens substantially contributed to the ongoing opioid epidemic in San Francisco. See Findings of Fact and Conclusions of Law regarding Walgreens (dkt. 1578). The FOFCOL was limited to liability, and the parties' proposed schedule for the abatement trial is due September 7, 2022. See Order Setting Scheduling Conference for Abatement Phase Trial (dkt. 1580). The abatement trial will determine the extent to which Walgreens must provide funds or other resources to help abate the opioid epidemic in San Francisco.

In advance of the abatement trial, the Court hereby directs Walgreens to show cause as to why the injunction order attached here as Exhibit A should not be entered forthwith. The injunction order is materially identical to the injunction order recently entered in the Track Three cases in the Northern District of Ohio. See In re Nat'l Prescription Opiate Litig., No. 18-OP-45032, dkt. 4611-1 (N.D. Ohio Aug. 17, 2022). The Track Three injunction order was itself modeled on the injunction that Walgreens recently entered to

1 resolve opioid-related litigation with the State of Florida. In re Nat'l Prescription Opiate  
2 Litig., No. 18-OP-45032, 2022 WL 3443614, at \*37 (N.D. Ohio Aug. 17, 2022).

3 In this case, the Court considers a substantially similar injunction order to be well  
4 warranted in light of the extensive evidence presented at trial proving that widespread  
5 deficiencies in Walgreens' compliance policies and practices directly contributed to the  
6 opioid epidemic in San Francisco. Walgreens has a duty to abate the opioid epidemic that  
7 it helped to create, and the terms of the injunction require Walgreens to make changes that  
8 will strengthen its compliance policies and practices and that will reduce the likelihood of  
9 further harm.

10 Walgreens shall file a statement setting forth its position on the injunction order by  
11 August 31, 2022, Plaintiff shall file a reply by September 7, 2022, and the Court will hear  
12 the matter at the September 13, 2022 scheduling conference.

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15 **IT IS SO ORDERED.**

16 Dated: August 22, 2022

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CHARLES R. BREYER  
United States District Judge

# **Exhibit A**

IN THE UNITED STATES DISTRICT COURT  
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CITY AND COUNTY OF SAN  
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Case No. 18-cv-07591-CRB

**INJUNCTION ORDER**

**I. INTRODUCTION**

A. Within 90 days of the date of this Order (except where this Order specifies a different implementation period), Walgreens shall implement the terms set forth in this Order (the “Terms”). References below to “the County” apply to the City and County of San Francisco. To the extent that Walgreens already has in place committees, departments, policies, or programs that satisfy the terms of this Order, no re-naming is required by this Order.

B. The Court will appoint an Administrator to oversee compliance with this Order. Appointment will be made after the Court receives recommendations from the parties, but the Administrator will be chosen by the Court. The Administrator's fees will be paid by Walgreens.

C. Overview

1. Walgreens will implement or maintain a Controlled Substance Compliance Program (“CSCP”).

2. The CSCP must include written standard operating procedures and/or corporate policies (the “CSCP Policies and Procedures”) required by this Order.

3. The CSCP shall apply during the term of this Order to Walgreens’ retail pharmacy stores within the County.

1                   4. Walgreens shall provide a copy of the relevant CSCP Policies and  
2 Procedures to the County and the Administrator. To the extent any implementation  
3 is expected to require additional time, Walgreens shall work together in good faith  
4 with the Administrator to establish a timeline for implementation.

5                   D. Compliance with Laws

6                   1. Walgreens' retail pharmacies must comply with applicable federal and  
7 California state laws, including regarding the dispensing of Controlled Substances.  
8 The requirements of this Order are in addition to, and not in lieu of, any other  
9 requirements of federal or California state law. Nothing in this Order shall be  
10 construed as relieving Walgreens of the obligation to comply with all federal and  
11 California state and local laws, nor shall any of the provisions of the Order be  
12 deemed as permission for Walgreens to engage in any acts or practices prohibited  
13 by such laws.

14                  2. The Order is not intended to and shall not be interpreted to prevent  
15 Walgreens from taking or implementing any other compliance or policy steps  
16 necessary to address its retail pharmacies conformity with local, state, and federal  
17 legal requirements.

18                  3. In the event that Walgreens determines there is a conflict between the  
19 Order and the requirements of federal, state, or local laws, such that Walgreens  
20 determines it cannot comply with the Order without violating these requirements,  
21 Walgreens shall document such conflicts and notify the County and the  
22 Administrator that it intends to comply with the law to the extent necessary to  
23 eliminate the conflict. Within thirty (30) days after receipt of a notification from  
24 Walgreens referenced above, the County may request a meeting to discuss the  
25 conflict and Walgreens shall comply with any such reasonable request. In the event  
26 that Walgreens and the County cannot agree, they may seek relief and a resolution  
27 from the Administrator. Administrator decisions are appealable to the Court.  
28 Nothing in this paragraph shall (i) limit the right of the County to disagree with  
Walgreens as to the impossibility of compliance and to seek to enforce the Order  
accordingly; or (ii) be deemed to relieve Walgreens from following any  
subsequently enacted law that is more restrictive than the provisions of the Order,  
or from following the Order if they are more restrictive than applicable laws, to  
the extent Walgreens can adhere to both the Order and the provisions of local, state  
or federal law.

                  4. In the event that any action, administrative or otherwise, is commenced  
against Walgreens, any of its retail pharmacies, or its pharmacy personnel as a  
result of Walgreens' obligations under this Order in the County, the County or  
Administrator will make best efforts to intervene and seek dismissal or to  
otherwise assist in achieving resolution, including by certifying that the County's  
and/or Administrator's position is that Walgreens should not be held liable for  
actions required by this Order.

5. Walgreens shall retain all records it is required to create pursuant to its obligations hereunder in an electronic or otherwise easily accessible format for the term of this Order. Nothing in this Order shall waive any applicable privilege that may be asserted over any such record.

## II. TERM AND SCOPE

A. The term of the Order shall be 15 years from the Effective Date, unless otherwise specified herein.

B. This Order shall apply to Walgreens' operation of any retail pharmacy store that dispenses Controlled Substances to Patients within the County.

## III. DEFINITIONS

A. The term "Controlled Substances" means those substances designated under schedules II-V pursuant to the federal Controlled Substances Act and the laws and regulations of the State that incorporate the federal Controlled Substances Act.

B. The term "Designated Controlled Substances" shall include (a) oxycodone; (b) hydrocodone; (c) hydromorphone; (d) oxymorphone; (e) morphine; (f) methadone; and (g) fentanyl.

C. The term "Prescriber" means any individual that has written a prescription, whether legally valid or not, that is presented to one of Walgreens' retail pharmacy stores in the County.

D. The term "Patient" means any individual who receives a prescription for a Designated Controlled Substance from a Prescriber, whether legally valid or not, and attempts to fill it at one of Walgreens' retail pharmacy stores in the County.

## IV. CONTROLLED SUBSTANCE COMPLIANCE PERSONNEL

A. Walgreens shall designate a Chief Controlled Substance Compliance Officer, or other appropriately titled position, to be a member of the Controlled Substance Compliance Committee (described below in Section VI), and to oversee a Controlled Substance Compliance Department and Walgreens' compliance with this Order. As used in this Order, the terms "Controlled Substance Compliance Committee" and "Controlled Substance Compliance Department" refer to the entity or entities, however titled, that carry out the functions required by this Order. Notwithstanding the preceding sentence, to the extent an existing position, committee or department carries out the functions required by this Order, any other functions undertaken by such position, committee or department shall not be subject to this Order or oversight by the Administrator pursuant to this Order. The position, committee and department discussed in this subsection and below may bear different names and need not be limited to the roles and functions set forth herein.

B. The Chief Controlled Substance Compliance Officer shall have knowledge of and experience with the laws and regulation of Controlled Substances.

1 C. The Chief Controlled Substance Compliance Officer shall provide at least  
2 quarterly reports to the Controlled Substance Compliance Committee and the  
3 Administrator regarding Walgreens' compliance with this Order, including the  
4 implementation of any changes to the CSCP Policies and Procedures required by this  
5 Order.

6 D. Staffing levels of Walgreens' Controlled Substance Compliance Department shall  
7 be reviewed periodically, but at least on an annual basis, by Walgreens' Controlled  
8 Substance Compliance Committee, to assess whether such staffing levels are sufficient  
9 for the Controlled Substance Compliance Department to comply with this Order. This  
10 review shall include consideration of relevant developments in technology, law, and  
11 regulations.

12 E. Throughout the term of this Order, Walgreens shall maintain a telephone and email  
13 hotline(s) (the "Hotline") to permit employees and/or Patients to anonymously report  
14 suspected inappropriate or illegitimate dispensing, prescribing or diversion of Designated  
15 Controlled Substances, violations of the CSCP Policies and Procedures, this Order,  
16 Walgreens' company policy, or other applicable law. Walgreens shall publish its Hotline  
17 contact information to its employees and Patients in the County. Walgreens shall maintain  
18 for the duration of this Order a record of each complaint made to the Hotline regarding  
19 Designated Controlled Substances and documentation regarding any investigation or  
20 response to such complaints. Nothing herein shall require Walgreens to investigate a  
21 pharmacist's professional judgment to refuse a prescription that the pharmacist believes  
22 was prescribed or is being used for other than a legitimate medical purpose or that the  
23 pharmacist believes was not prescribed by an individual Prescriber acting in the usual  
24 course of his or her professional practice.

## 25 V. INDEPENDENCE

26 A. Walgreens' Controlled Substance Compliance Department personnel, the  
27 pharmacy personnel who work at Walgreens' retail pharmacies within the County, and  
28 field personnel who supervise such pharmacy personnel (together, "CSCP Employees")  
shall not be compensated in whole or in part by commissions, bonuses, incentives or any  
other monetary or non-pecuniary benefit that depends in any part on revenue or  
profitability targets or expectations specific to sales of Controlled Substances. Nothing in  
this Order shall be interpreted to prevent compensation of employees based on sales  
volumes, revenue or profitability targets/expectations for enterprise-, store- or pharmacy-  
wide sales.

B. No CSCP Employees may be terminated, suspended, threatened with or face any  
other negative employment consequence for failing to meet any revenue or profitability  
targets/expectations specific to sales of Controlled Substances.

C. To the extent necessary to comply with this section, Walgreens' Controlled  
Substance Compliance Committee shall review, modify, and implement any changes to  
any compensation and non-retaliation policies specific to the sale or dispensing of



Designated Controlled Substances.

## **VI. OVERSIGHT**

A. To the extent not already established, Walgreens shall establish a compliance committee, however titled, that includes representatives from its respective legal, compliance, pharmacy operations, and asset protection departments, however named, to provide oversight over the CSCP and its compliance with this Order. For the purposes of reference herein, this committee, however named, shall be referred to as the “Controlled Substance Compliance Committee.” Walgreens shall maintain its Controlled Substance Compliance Committee for the duration of the term of this Order. The Chief Controlled Substance Compliance Officer of Walgreens shall be a member of the Controlled Substance Compliance Committee.

B. Walgreens’ Controlled Substance Compliance Committee shall have regular meetings during which the Chief Controlled Substance Compliance Officer shall report on, and the Controlled Substance Compliance Committee shall review, among other things, (a) the Prescription Validation Process, including the CSCP Policies and Procedures on identifying and resolving Patient, Prescriber and Prescription Red Flags; (b) the training required under this Order; (c) proactive due diligence and site visits; (d) the Prescriber Review Processes; (e) significant new national and regional diversion trends involving Controlled Substances; (f) Walgreens’ adherence to this Order and applicable laws and regulations; and (g) any technology, staffing, or other resource needs for the CSCP. The Controlled Substance Compliance Committee shall have access to all CSCP reports described in the following subsection.

C. On an annual basis, Walgreens’ Controlled Substance Compliance Committee shall provide a written report to the President, Chief Financial Officer, Chief Legal Officer, and the Chief Compliance Officer (however such positions or committees are named at the time), and the Administrator, outlining: (a) Walgreens’ adherence to, and any deviations from, this Order; (b) the allocation of resources sufficient to comply with this Order; and (c) any revisions to the CSCP that the Controlled Substance Compliance Committee has approved. The Compliance Committee shall document in its minutes its review of the annual Controlled Substance Compliance Committee reports.

D. Walgreens, through its Controlled Substance Compliance Departments and Committees, shall, at least once every year, review and oversee any enhancements to the CSCP Policies and Procedures and systems for dispensing activity that the Controlled Substance Compliance Committee deems necessary.

E. Walgreens’ Controlled Substance Compliance Committee shall be responsible for the approval of all material revisions to the CSCP Policies and Procedures, provided that nothing herein shall prevent Walgreens from implementing changes to the CSCP Policies and Procedures pending such review and approval.

## **VII. MANDATORY TRAINING**

A. The CSCP Policies and Procedures shall be published in a form and location



readily accessible to all pharmacy and compliance personnel at each of Walgreens' retail pharmacy stores in the County. Online availability is sufficient, so long as pharmacy and compliance personnel have access to a computer with access to the CSCP Policies and Procedures.

B. Within 90 days of the date of this Order, to the extent not already in place, Walgreens shall implement policies and procedures requiring all CSCP Employees to complete trainings on the CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and its corresponding responsibility.

C. On an annual basis for the duration of the Order, Walgreens shall test its CSCP Employees, and any contractors serving as pharmacists or pharmacy technicians in its retail pharmacies in the County, on their knowledge regarding CSCP Policies and Procedures required under this Order, including with respect to the Prescription Validation Process and their corresponding responsibility.

D. It shall be a part of the CSCP Policies and Procedures and all trainings of all CSCP Employees required under this Order that pharmacists shall refuse to dispense Controlled Substances that they believe were prescribed or are being used for other than a legitimate medical purpose or that they believe were not prescribed by an individual Prescriber acting in the usual course of his or her professional practice.

E. All trainings required under this Order shall also make clear that pharmacists will not be penalized in any way for refusing to fill prescriptions for Controlled Substances or for conducting Due Diligence the pharmacist deems necessary pursuant to their corresponding responsibility.

### **VIII. THE PRESCRIPTION VALIDATION PROCESS**

A. As part of its CSCP, to the extent not already in place, Walgreens shall have a Prescription Validation Process in the CSCP Policies and Procedures, as further described and set forth in this section, that each pharmacist employed by Walgreens at a retail pharmacy in the County is directed to follow when dispensing a prescription for a Controlled Substance.

B. Walgreens' CSCP Policies and Procedures shall provide that a Red Flag will be considered "resolved" if, after further investigation as described below, and given other facts and circumstances surrounding the prescription, a pharmacist determines, in his or her professional judgment, that the facts that triggered the Red Flag do not lead him or her to believe that the prescription was written or is being submitted for an illegitimate medical purpose or outside the usual course of a Prescriber's professional practice.

C. Walgreens' CSCP Policies and Procedures shall provide that if a pharmacist identifies any "Patient Red Flags" associated with a Controlled Substance prescription (described in Section IX(A) below), before filling the prescription the pharmacist must resolve them; and that the method of resolution falls within the judgment of the pharmacist

1 and may include reviewing the Patient's profile and history with Walgreens, calling the  
2 Prescriber or Prescribers if appropriate, speaking with the Patient if appropriate, calling  
3 on the pharmacist's pre-existing knowledge of the Patient or Prescriber, reviewing  
4 available PDMP data, and/or reviewing other data or information available to the  
5 pharmacist.

6 D. Walgreens' CSCP Policies and Procedures shall provide that, except as allowed  
7 by California law, a pharmacist may only fill a Controlled Substance prescription  
8 electronically transmitted by a Prescriber for such drugs; that if the pharmacist identifies  
9 any other "Prescription Red Flags" (described in Section IX(B) below), the pharmacist  
10 must resolve them; and that the method of resolution falls within the judgment of the  
11 pharmacist and may include reviewing the Patient's profile and history with Walgreens,  
12 calling the Prescriber or Prescribers if appropriate, speaking with the Patient if  
13 appropriate, calling on the pharmacist's preexisting knowledge of the Patient or Prescriber,  
14 reviewing available PDMP data, and/or reviewing other data or information available to  
15 the pharmacist.

16 E. Walgreens must put in place, to the extent not already in place, systems at its retail  
17 pharmacies in the County to check the licensure status of a Prescriber of Controlled  
18 Substances through a regularly updated prescriber database, to the extent such information  
19 is reasonably available for such purposes. The dispensing system shall block a Controlled  
20 Substance prescription from being filled if the prescriber database check reflects a DEA  
21 registration or state license that has been suspended or revoked and likewise shall block from  
22 being filled under a Controlled Substance prescription written by a prescriber blocked by  
23 Walgreens under a prescriber review program. CSCP Policies and Procedures shall require  
24 that if a pharmacist identifies any Prescriber Red Flags, the pharmacist must resolve them,  
25 and that the method of resolution falls within the judgment of the pharmacist and may  
26 include reviewing Walgreens' records regarding the Prescriber, calling the Prescriber if  
27 appropriate, speaking with the Patient if appropriate, calling on the pharmacist's pre-  
28 existing knowledge of the Patient or the Prescriber, reviewing available PDMP data,  
and/or reviewing other data or information available to the pharmacist.

F. Walgreens' CSCP Policies and Procedures shall provide that the resolution of all  
Red Flags and Refusals-to-Fill identified by the pharmacist must be documented. The  
pharmacist must provide a clear description of the Red Flag(s) and either (i) how the Flag  
was resolved before the medication was dispensed, or (ii) the reasons why the pharmacist  
refused to dispense the medication. The documentation should provide sufficient  
details in order that any subsequent reviewer will have a clear understanding of how each  
Flag was resolved for any review or inquiry for auditing or regulatory purposes. Any such  
records shall be maintained for the duration of this Order.

G. Walgreens' CSCP Policies and Procedures shall provide that, even if all Red Flags  
are resolved, a pharmacist shall reject a prescription if, in his or her professional judgment,  
he or she believes that it was written or is being submitted for other than a legitimate  
medical purpose and/or was written outside the usual course of an individual Prescriber's  
professional practice.

**IX. RED FLAGS**

A. Notwithstanding any other Red Flags that Walgreens may identify in its CSCP Policies and Procedures, Walgreens shall identify in its CSCP Policies and Procedures the following “Patient Red Flags”:

1. A Patient seeks to fill a Designated Controlled Substance prescription more than three days prior to the contemplated exhaustion date of an earlier prescription of the same Designated Controlled Substance;

2. A Patient seeks to fill Designated Controlled Substance prescriptions from more than four Prescribers, from separate practices, in a given 6-month period;

3. A Patient resides more than 50 miles from Walgreens retail pharmacy where the Designated Controlled Substance prescription is submitted;

B. Notwithstanding any other Red Flags that Walgreens may identify in its CSCP Policies and Procedures, with respect to any Controlled Substance prescriptions, Walgreens shall identify in its CSCP Policies and Procedures the following potential “Prescription Red Flags:”

1. A prescription that fails to meet the requirements of law;

2. A prescription that appears altered;

3. A prescription written with misspellings suggesting the prescription may not have been written by a Prescriber;

4. A prescription using atypical abbreviations suggesting the prescription may not have been written by a Prescriber; and

5. A prescription written with multiple colors of ink or in multiple different handwritings.

C. Notwithstanding any other potential Red Flags that Walgreens may identify in its CSCP Policies and Procedures, with respect to any Prescriber of Controlled Substances, Walgreens shall identify in its CSCP Policies and Procedures the following potential “Prescriber Red Flags:”

1. A Prescriber provides a Patient with prescriptions for a Designated Controlled Substance, a benzodiazepine, and carisoprodol; and

2. A Prescriber has no office within 50 miles of the retail pharmacy store.

**X. PRESCRIBER REVIEW**

A. To the extent not already in place, Walgreens shall develop a process by which it regularly reviews the prescribing patterns and practices of Prescribers of Designated Controlled Substances (the "Prescriber Review Process"). The Prescriber Review Process shall employ algorithms, or other means, to review Walgreens' retail dispensing data for potential Prescribers of concern. Once Walgreens identifies through its process a Prescriber for further investigation, the review of a Prescriber shall include review of his or her prescribing as contained in Walgreens' data and available licensing and disciplinary history. It may also include internet searches, interviews and other information gathered in the discretion of the employees operating the Prescriber Review Process.

B. If after the Prescriber Review Process Walgreens has not resolved its concerns of illegitimate prescribing, then Controlled Substance prescriptions written by the Prescriber shall be blocked from being filled by Walgreens' retail pharmacies in the County, with an opportunity at the discretion of Walgreens for the prescriber to seek future reinstatement by providing information to Walgreens that may resolve its concerns. This block shall be on top of and in addition to any block based on a Prescriber's licensure. On written demand by the County or the Administrator, Walgreens shall provide the names of the prescribers who it has identified for investigation and/or whose prescriptions it has blocked.

**XI. PROACTIVE DUE DILIGENCE AND SITE VISITS**

A. During the term of this Order, Walgreens shall conduct periodic proactive compliance reviews of its retail pharmacy stores in the County to assist with the identification of potential compliance issues related to the dispensing of Designated Controlled Substances at its retail pharmacy stores in the County. This may be satisfied by the use of algorithms, or other electronic means, to analyze data associated with each pharmacy to identify particular pharmacies for review. Documentation of any resulting reviews shall be maintained by Walgreens and made accessible to all Controlled Substance Compliance Department personnel upon request for the duration of this Order.

B. During the term of this Order, Walgreens' field personnel shall also conduct site visits to each of its retail pharmacy stores in the County each year for the duration of the Order. Operating procedures shall specify that any concerns identified with the dispensing of Designated Controlled Substances shall be reported to the Controlled Substance Compliance Department. The Controlled Substance Compliance Department shall maintain documentation of any such reported concerns.

C. During the term of this Order, to the extent not already in place, Walgreens shall put in place processes to oversee inventory, record keeping, and theft and loss prevention controls at its retail pharmacy stores in the County.

D. The CSCP Policies and Procedures shall require that site visit reports, if any, related to the dispensing of Designated Controlled Substances shall be maintained by Walgreens and provided to all Controlled Substance Compliance Department personnel for the duration of this Order and an annual report shall be provided to the Administrator.

**XII. CONTROLLED SUBSTANCE DISPOSAL**

A. Walgreens' retail pharmacies in the County shall make available or display information to all Patients receiving a Designated Controlled Substance about the need to dispose and the proper disposal of unused Controlled Substances and the availability of disposal boxes, pouches or containers for purchase from Walgreens, or other products commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home.

B. At each of its retail pharmacies in the County, Walgreens shall make available to Patients at its actual cost (per generally accepted accounting principles) a pouch or other container or product commercially manufactured to allow for the safe disposal of Controlled Substances and medications at home. Walgreens shall maintain sufficient written documentation supporting its actual cost for the duration of this Order.

**XIII. NALOXONE DISPENSING**

A. To the extent not already in place, Walgreens shall obtain a non-patient-specific standing order covering each of its retail pharmacies in the County allowing for the dispensing of naloxone or other overdose reversal medications to the fullest extent allowable under California law.

B. To the extent that the County and/or the State of California obtain or enter into an agreement with a manufacturer of naloxone or other overdose reversal medication to provide naloxone or an overdose reversal medication to the County and/or State for free or at cost, Walgreens shall dispense that naloxone or other overdose reversal medication at its actual cost for dispensing that naloxone or other overdose reversal medication (time and expense). Upon request by the County and/or State to dispense such medication, in the course of arranging logistics with the County and/or State, Walgreens shall provide the County and the Administrator with its calculation of the actual cost to dispense.

**XIV. FRAUD, THEFT AND LOSS PREVENTION**

In addition to complying with all fraud, theft and loss procedures, policies and precautions required by state and federal law, Walgreens shall maintain information regarding the receipt and disposition of inventory of all Designated Controlled Substances for each retail pharmacy in the County.

**XV. REPORTING TO LAW ENFORCEMENT**

To the extent not already in place, Walgreens shall implement standard operating procedures directing its employees to report any confirmed forged prescriptions to state or local law enforcement authorities within 7 days of completing any review of such prescription or conduct. The County shall provide appropriate contact information for such reports. Walgreens shall keep a record of all forged prescriptions in its database accessible to all pharmacists in the area and shall track all reports made to the DEA, local law enforcement and state agencies concerning Designated Controlled Substances. Walgreens shall comply with all statutes and regulations requiring the reporting of thefts and losses of Controlled Substances.



**XVI. ENFORCEMENT OF ORDER TERMS****A. Notice of Potential Violations and Opportunity to Cure.**

1. A “Potential Violation” occurs when the County determines, after appropriate investigation and due diligence, that Walgreens is not in substantial compliance with a material aspect of this Order. A Potential Violation may be for a single retail pharmacy.

**2. Potential Violation Discovered by the County.**

a. In the event a Potential Violation is identified by the County, the County shall notify Walgreens and the Administrator in writing (the “County Notice”).

b. Within thirty (30) days of receipt of the County Notice, Walgreens shall provide a written response to the County and the Administrator. The response shall include Walgreens’ position as to the act(s) of non-compliance with this Order’s Terms, including, possibly, a statement setting forth why Walgreens believes it is in substantial compliance with the relevant provision(s) or a statement explaining how the Potential Violation has been addressed.

c. If the County and/or the Administrator wish to meet with Walgreens, Walgreens shall promptly make itself available for such a meeting.

3. If, after review of a written response and any meeting, the Administrator believes that a Potential Violation is ongoing or has not been substantially addressed, the Administrator will:

a. Provide written notice to Walgreens, and

b. Work in conjunction with the County and Walgreens to devise, within thirty (30) days, a corrective action plan (“Corrective Action Plan”) to remedy such Potential Violation, including a reasonable period for implementation of such plan.

4. Within 60 days after implementing the Corrective Action Plan, Walgreens will provide a written compliance update to the County and the Administrator and make itself available to meet if requested.

a. If after reviewing the compliance update and any meeting, the County believes a Potential Violation remains ongoing or has not been substantially addressed, the County may seek to enforce this Order before the Administrator.

b. In the event the Administrator agrees that a Potential Violation remains ongoing or has not been substantially addressed, the Administrator may order compliance with this Court's Order and may award any other relief permitted by law.

5. If a Walgreens fails or refuses to provide a written response, to devise or implement a Corrective Action Plan or to provide a compliance update as required by subsections A(2), A(3) and/or A(4), upon a request made by the County, the Administrator may order compliance with this Court's Order and may award any other relief permitted by law.

6. If, after review of a written response and any meeting, pursuant to subsection A(2) or A(3), above, the Administrator concludes that a Potential Violation is not ongoing or has been substantially addressed, the Administrator will provide written notice of this conclusion to Walgreens as soon as reasonably possible.

7. Any party may appeal a decision from the Administrator to the Court for a final decision pursuant to Fed. R Civ. P. 53(f).

B. Enforcement Action.

The County will follow the entire process outlined above prior to taking any other court or administrative action, except the County may pursue an action that it concludes in good faith is necessary to address (i) an immediate threat to the health, safety, or welfare of the citizens of the County, or (ii) a public emergency requiring immediate action. The County will make best efforts to provide reasonable notice to Walgreens prior to initiating any such action.

## **XVII. COMPLIANCE CERTIFICATION**

A. Walgreens' Chief Controlled Substance Compliance Officer shall, after diligent inquiry, complete an annual compliance certification.

B. The certification shall be provided to the Administrator annually for the duration of this Order.

C. The certification shall state:

"I understand the compliance requirements and responsibilities as they relate to [insert name of department], an area under my supervision. My job responsibilities include promoting compliance with regard to the [insert name of department] with all applicable statutory requirements, obligations of the Order, and applicable policies, and I have taken steps to promote such compliance. To the best of my knowledge, the [insert name of department] is in compliance with the obligations of the Order. I understand that this certification is being provided to and relied upon by the



U.S. District Court for the Northern District of California.”

D. If the Chief Controlled Substance Compliance Officer is unable to provide such a certification, he or she shall provide a written explanation of the reasons why he or she is unable to provide the certification outlined above to the Administrator.

E. Upon written demand by the County or the Administrator, Walgreens shall provide within a reasonable time after request the below materials.

1. Any specific, non-privileged documents reviewed by the Chief Controlled Substance Compliance Officer solely to make his/her certification, not including documents reviewed in the course of his/her duties throughout the year that provide him/her with relevant knowledge;

2. The current versions of the CSCP Policies and Procedures that are required by this Order;

3. The names of California Prescribers of Designated Controlled Substances who the Settling Pharmacy has flagged for investigation and/or whose prescriptions it has blocked as part of its Prescriber Review Process; or

4. With regard to a particular retail pharmacy store in the County, any non-privileged reports related to that pharmacy store prepared pursuant to the processes outlined in Section XI.A.

F. Nothing in this Order shall be interpreted to abrogate Walgreens’ applicable privileges or protections from disclosure, including without limitation those related to the attorney-client privilege, the attorney work product doctrine, and the patient-safety work product privilege. Nothing in this Order shall require Walgreens to provide or produce any such privileged or protected materials.

G. To the extent that the above records contain personal health information of patients, the personal health information of patients shall be redacted and the presence of personal health information shall not be a reason to not produce any category of documents. To the extent that city, state, or zip code related information is contained within the above records and does not constitute personal health information of patients, Walgreens shall provide such information upon written request.

## **XVIII. RECORDKEEPING**

Walgreens shall retain records they are required to create pursuant to its obligations hereunder in an electronic or otherwise readily accessible format. In addition to the prescription data regularly provided to the State of California through its prescription drug monitoring program and all of the other records to which the State of California has access under its pharmacy regulations, including without limitation through its on-site inspections of retail pharmacies, the County shall have the right to review the CSCP Policies and Procedures discussed herein. Nothing in these terms shall prohibit the County

from issuing a lawful subpoena for records pursuant to an applicable law.

**XIX. CHANGES AND MODIFICATIONS**

A. The Court may, under its continuing jurisdiction over the abatement relief awarded, amend or modify this injunctive relief order as required in the interest of justice.

B. Nothing in this Order shall be construed to prohibit Walgreens from implementing improvements or enhancements or from otherwise evolving its systems and practices.

**IT IS SO ORDERED.**

Dated:

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CHARLES R. BREYER  
United States District Judge

United States District Court  
Northern District of California